DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 16, 2015

NeoMetrics, Inc.
Dave Liebl
President and Chief Technology Officer
2605 Fernbrook Lane North, Suite J
Plymouth, MN 55447

Re: K150225
Trade/Device Name: NovaGold™ High Performance Guidewire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: January 30, 2015
Received: February 2, 2015

Dear Dave Liebl,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150225

Device Name
NovaGold™ High Performance Guidewire

Indications for Use *(Describe)*
The NovaGold Guidewire is intended for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts, and to aid in the placement of diagnostic and therapeutic devices during endoscopic procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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6.0 510(k) Summary

Submitter:	NeoMetrics, Inc. 2605 Fernbrook Lane North, Suite J Plymouth, MN 55447
Contact Person:	Dave Liebl, President and Chief Technology Officer 2605 Fernbrook Lane North, Suite J Plymouth, MN 55447
Date Prepared:	January 30, 2015
Trade Name:	NovaGold™ High Performance Guidewire
Classification:	Class II Regulation Number: 21 CFR 876.1500.
Product Code:	OCY
Predicate Device:	The subject device is substantially equivalent to K133076; NovaGold High Perfomance Guidewire manufactured by NeoMetrics, Inc.
Device Description:	The NovaGold Guidewire is constructed from a steerable, metallic core with a PTFE polymer coating over the shaft. A hydrophilic coating is applied over the distal portion of the device. The guidewire has a radiopaque, floppy tip.
Indication for Use:	The NovaGold Guidewire is intended for use in selective cannulation of the biliary ducts including the common bile, pancreatic, cystic, right and left hepatic ducts, and to aid in the placement of diagnostic and therapeutic devices during endoscopic procedures.
Principle of Operation:	The NovaGold Guidewire is manually inserted and advanced to the target region.
Functional and Safety Testing:	To verify that device design met functional and performance requirements, representative samples of the device underwent bench testing in accordance to applicable standards and guidances. These data provides an acceptable assurance of the safety and effectiveness of the NovaGold guidewire and demonstrated the device is equivalent to the predicate.

Comparative Technology Characteristics	A comparison of the characteristics of the proposed device and the predicate device shows the NovaGold guidewire to have the same technological characteristics to the predicate which has received 510(k) clearance. • Identical intended use • Identical operating principle • Identical packaging and sterilization process • Identical overall design, materials of construction, and technology Identical: o Nominal diameter: 0.018” o Guidewire lengths: 260 and 480 cm o Nitinol alloy core wires o Distal radiopaque tip o Lubricious coatings
Non-Clinical Tests Submitted	The following tests were performed to support NovaGold’s substantial equivalence. o Fracture resistance o Flex resistance o Tensile strength o Torqueability o Torque Strength o Tip flexibility o Distal fatigue resistance
Conclusion:	NeoMetrics Inc. considers the NovaGold guidewire to be equivalent to the predicate device. This conclusion is based upon the fact that device has an equivalent intended use, and there are no differences that raise new types of questions of safety and effectiveness.